

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

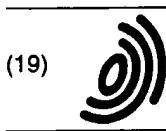
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.



(19)

Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 1 266 631 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
18.12.2002 Bulletin 2002/51

(51) Int Cl.7: A61B 17/12

(21) Application number: 02254120.5

(22) Date of filing: 13.06.2002

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE TR**
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: 13.06.2001 US 880506

(71) Applicant: **Cordis Neurovascular, Inc.**
Miami Lakes, Florida 33014 (US)

(72) Inventors:
• Jones, Donald K
Lauderhill, FL 33351 (US)
• Mitelberg, Vladimir
Aventura, FL 33180 (US)

(74) Representative: **Belcher, Simon James**
Urquhart-Dykes & Lord
Tower House
Merrion Way
Leeds LS2 8PA (GB)

(54) Embolic coil

(57) A coil for occluding the vasculature of a patient. The coil has a textured surface which provides improved platelet adhesion compared to a non-textured surface, to promote clotting. The coil comprises a platinum-tungsten alloy wire and the texturing is performed by abra-

sion or sandblasting to provide substantially uniform roughness comprising pockets having diameters of about 0.125 µm to about 50 µm and depths of about 0.25 µm to about 20 µm.

EP 1 266 631 A1

Description

[0001] The present invention concerns an embolic coil. The coil of the invention can be used to occlude the vasculature of a patient.

[0002] A known technique for treating a brain aneurysm of a patient includes the placement of embolic coils within the aneurysm. To this end, a catheter is introduced into the vessel leading to the aneurysm, and embolic coils are delivered to pack and fill the aneurysm. Ordinarily, a deployment system is used to deliver the coils, via the catheter, to the aneurysm, such as the deployment system disclosed in US-6113622.

[0003] The embolic coils act to reduce the blood flow inside of the aneurysm. Typically the embolic coils provide a mechanical blockage to the blood flow in the aneurysm. In this manner, the stagnation of blood that is obtained prevents the blood flow from rupturing the aneurysm. However, such stagnation forms a thrombus inside the aneurysm, that eventually can get resorbed.

[0004] The present invention provides a technique for blocking blood flow with the addition of platelet adhesion to the embolic coils. This allows tissue to grow, and the thrombus that forms, instead of being resorbed, has the ability to be organized into fibrous scar tissue. Such fibrous scar tissue achieves long term healing of the aneurysm in contrast to the use of embolic coils that can move around with the result that the formed thrombus may be resorbed.

[0005] The coil of the invention is useful for occluding the vasculature of a patient. In addition to embolising an aneurysm, the coil can also be used for embolising a vessel for vessel sacrifice; for reducing or blocking blood flow to an arterial-venous malformation or to a fistula; and for blocking blood flow to tumours.

[0006] In one aspect, the present invention provides an embolic coil formed of wire and having a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

[0007] A coil according to the invention is introduced into a patient's vasculature, preferably together with a plurality of other similar embolic coils. The textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

[0008] The adhesion of platelets to the coil of the invention encourages tissue formation and can prevent a coil from moving around within an aneurysm.

[0009] Preferably, the surfaces of the embolic coils can be textured by abrasion or sandblasting. Preferably, the embolic coil comprises a platinum-tungsten alloy wire. Preferably, the embolic coil has a substantially uniform roughness comprising pockets having diameters of between about 0.125 µm (microns) and about 50 µm (microns) and depths between about 0.25 µm (microns) to 20 µm (microns).

[0010] In another aspect, the invention provides an embolic coil formed of a platinum alloy wire and having

a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesions compared to a non-textured surface to promote clotting, the coil including a proximal portion

5 and a distal portion, in which the proximal portion is relatively smooth and said textured surface is on said distal portion, the textured portion having substantially uniform roughness comprising pockets having diameters between about 0.125 µm (microns) and about 50 µm (microns) and depths between about 0.25 µm (microns) and about 20 µm (microns).

[0011] The present invention will now be described by way of example with reference to the accompanying drawings, in which:

15 Fig. 1 is a view of an embolic coil constructed in accordance with the principles of the present invention.

20 Fig. 2 is a diagram of a patient's brain aneurysm having the coils of the present invention implanted therein.

Fig. 3 is a photomicrograph, enlarged 233x, showing a portion of an embolic coil with a smooth surface, prior to texturing.

25 Fig. 4 is a photomicrograph, enlarged 233x, showing a similar portion of an embolic coil as the Fig. 3 portion, but with texturing.

Fig. 5 is a photomicrograph, enlarged 3880x, showing a portion of an embolic coil with a smooth surface, prior to texturing.

30 Fig. 6 is a photomicrograph, enlarged 3880x, showing a similar portion of an embolic coil as the Fig. 5 portion, but with texturing.

35 [0012] Referring to the drawings, Fig. 1 shows an embolic coil constructed in accordance with the principles of the present invention. Embolic coil 10 is formed by winding a platinum-tungsten alloy wire into a helical configuration. In the illustrative embodiment, the diameter

40 of the wire is generally in the range of about 0.0038 to 0.20 mm (0.0015 to 0.008 inches). The outside diameter of the coil 10 is preferably in the range of about 0.15 to 1.40 mm (0.006 to 0.055 inches). The embolic coil 10 shown in Fig. 1 may be straight or may take the form of

45 various configurations, including the form of a helix, a random shape configuration, or a coil within a coil configuration.

[0013] The details of construction of an example embolic coil, although no limitation is intended, is disclosed in US-6063100.

[0014] With the helical wound coil as illustrated in Fig. 1, the coil is provided with a seal plug 12 at its distal end and another seal plug 14 at its proximal end. Seal plugs 12 and 14 serve to prevent the flow of fluid through the lumen of the coil 10.

[0015] A suitable material from which the coil can be formed is a platinum-tungsten alloy comprising 92% platinum and 8% tungsten. Preferably, the outer surface

of the coil is textured by abrasion or sandblasting. To this end, alumina particles having a diameter of 50 µm (micron) are used to texture the surface of the wire that is used to form the coils, prior to the formation of the helical coils. It has been found that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization.

[0016] The texturization provides a uniform roughness comprising pockets having diameters of between about 0.125 µm (microns) and about 50 µm (microns) and depths of between about 0.25 µm (microns) and about 20 µm (microns). The roughness is uniform throughout the coil except if the coil is used with a detachment system such as disclosed in US-6113622 or US-6063100, a proximal portion of the coil is not textured in order for it to have a proper seal with a gripper so that it can released easily.

[0017] Fig. 2 is a diagrammatic view of a patient's vessel 16 leading to an aneurysm 18 into which a number of embolic coils 10 have been introduced. The coils are introduced in a manner known in the art, by introducing a catheter into the vessel 16, then introducing a deployment device via the catheter to deliver the embolic coils, one by one, to the aneurysm 18.

[0018] SEM micrographs of the non-textured vs. textured coils are provided in Figs. 3-6. Referring to Fig. 3, a portion of a non-textured coil is shown in a micrograph having an enlargement of 233x. Fig. 4 shows a similar coil with a 233x enlargement, but with texture that has been provided by sandblasting as disclosed above. Fig. 5 is a greatly enlarged micrograph, having an enlargement of 3880x, of the coil sample of Fig. 3 and Fig. 6 is a greatly enlarged micrograph having an enlargement of 3880x, of the coil sample of Fig. 5.

[0019] Testing was conducted using radio-labelled platelets to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increased in the platelet deposition of about fifty percent over the non-texture coils.

[0020] It can be seen that by using embolic coils that have been textured, there is superior platelet adhesion which promotes clotting and subsequent endothelialization. A texturing technique has been disclosed that is simple and does not require expensive or elaborate equipment to modify the coils. In the illustrative embodiment the texturing technique does not require coating or ion implantation, thereby avoiding the importation of any new materials to the coil that would require new biocompatibility testing.

to promote clotting.

2. An embolic coil as defined in claim 1, in which said embolic coil comprises a platinum-tungsten alloy wire.
3. An embolic coil as defined in claim 1, in which said embolic coil includes a proximal portion and a distal portion; said proximal portion being relatively smooth and said textured surface being on said distal portion.
4. An embolic coil as defined in claim 1, in which said embolic coil has substantially uniform roughness comprising pockets having diameters between about 0.125 µm (microns) and about 50 µm (microns).
5. An embolic coil as defined in claim 4, in which said pockets have depths of between about 0.25 µm (microns) and about 20 µm (microns).
6. An embolic coil formed of a platinum alloy wire and having a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesions compared to a non-textured surface to promote clotting, the coil including a proximal portion and a distal portion, in which the proximal portion is relatively smooth and said textured surface is on said distal portion, the textured portion having substantially uniform roughness comprising pockets having diameters between about 0.125 µm (microns) and about 50 µm (microns) and depths between about 0.25 µm (microns) and about 20 µm (microns).

Claims

1. An embolic coil formed of wire and having a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesion compared to a non-textured surface,

55

FIG. 1

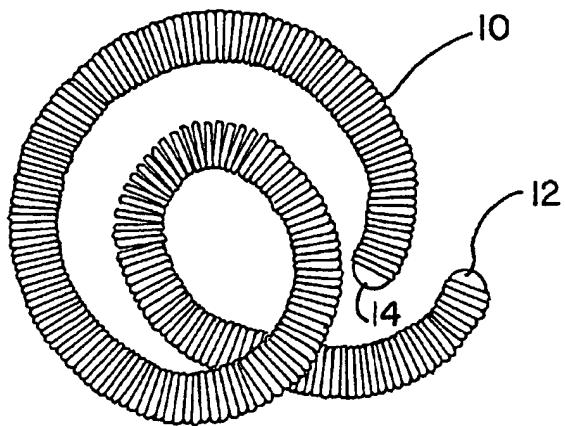
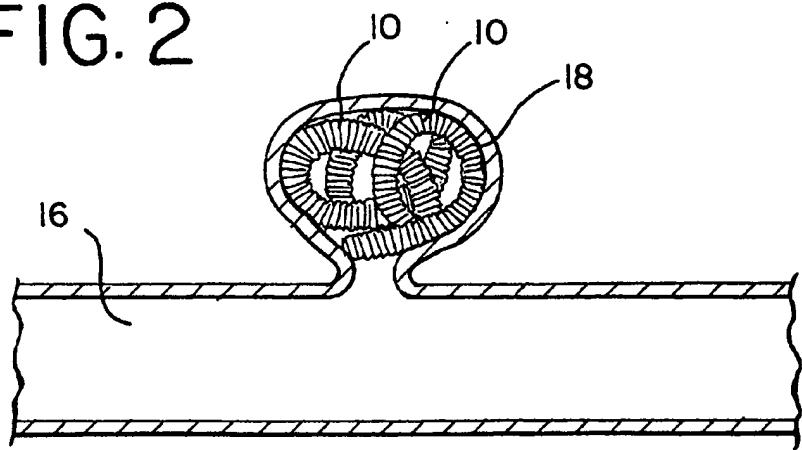


FIG. 2



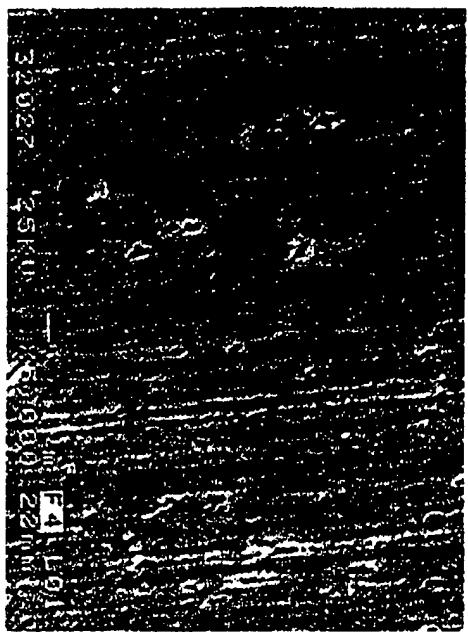


FIG. 5



FIG. 3

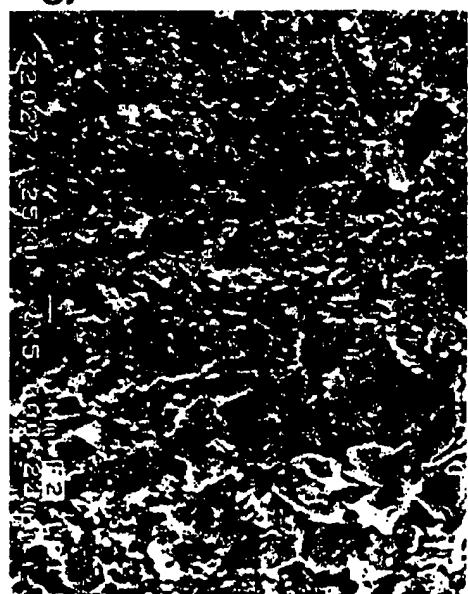
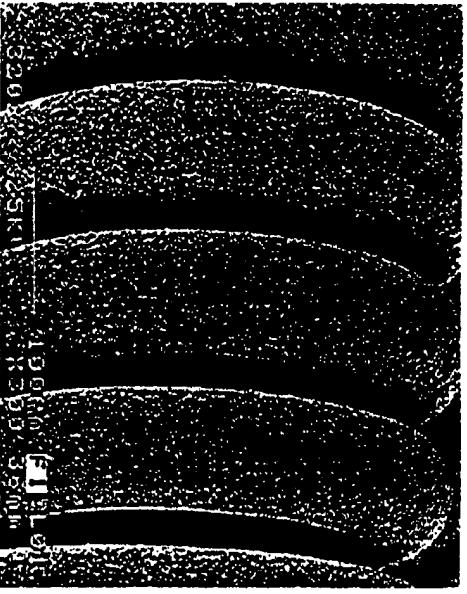


FIG. 6





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 02 25 4120

DOCUMENTS CONSIDERED TO BE RELEVANT									
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)						
X	FR 2 696 636 A (BALT SA) 15 April 1994 (1994-04-15) * page 1, line 31 - line 35; figure 1 *	1	A61B17/12						
Y	US 5 911 731 A (DOAN HONG ET AL) 15 June 1999 (1999-06-15) * column 2, paragraph 6 - paragraph 7 * * column 4, paragraph 2 - paragraph 6; figure 10B *	2							
Y	---								
A	US 6 024 754 A (ENGELSON ERIK T) 15 February 2000 (2000-02-15) * column 2, paragraph 5 - column 3, paragraph 3 * * column 6, paragraph 1 - column 6, paragraph 4 *	1-6							
A	---								
A	WO 98 02100 A (ANSON MEDICAL LTD ;QURESHI SHAKEEL (GB); REIDY JOHN (GB); ANSON AN) 22 January 1998 (1998-01-22) * page 3, paragraph 6 - page 4, paragraph 3 * * page 6, paragraph 2 - page 6, paragraph 3 *	1-6							

			TECHNICAL FIELDS SEARCHED (Int.Cl.7)						
			A61B A61F A61L						
<p>The present search report has been drawn up for all claims</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Place of search</td> <td style="width: 33%;">Date of completion of the search</td> <td style="width: 34%;">Examiner</td> </tr> <tr> <td>MUNICH</td> <td>22 October 2002</td> <td>Lundblad, H</td> </tr> </table>				Place of search	Date of completion of the search	Examiner	MUNICH	22 October 2002	Lundblad, H
Place of search	Date of completion of the search	Examiner							
MUNICH	22 October 2002	Lundblad, H							
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document							
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document									

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 02 25 4120

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
 The members are as contained in the European Patent Office EDP file on
 The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

22-10-2002

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
FR 2696636	A	15-04-1994	FR	2696636 A1	15-04-1994
US 5911731	A	15-06-1999	US	5645558 A	08-07-1997
			CA	2186768 A1	30-03-1997
			EP	0765636 A2	02-04-1997
			JP	3024071 B2	21-03-2000
			JP	9168541 A	30-06-1997
			EP	0743047 A2	20-11-1996
			JP	9094300 A	08-04-1997
			US	6090125 A	18-07-2000
			US	5766219 A	16-06-1998
US 6024754	A	15-02-2000	US	5749894 A	12-05-1998
WO 9802100	A	22-01-1998	AU	3550897 A	09-02-1998
			EP	0915678 A1	19-05-1999
			WO	9802100 A1	22-01-1998
			JP	2000514336 T	31-10-2000
			US	2002099437 A1	25-07-2002
			US	6432134 B1	13-08-2002

EPO FORM P0459
 For more details about this annex : see Official Journal of the European Patent Office, No. 12/82